DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Kansas City District
Southwest Region
11630 W. 80th Street
Lenexa, Kansas 66214
Telephone: (913) 752-2100

April 29, 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
Ref. KAN 2004-09

Allan J. Kramer, Ph.D., President
Sioux Biochemical, Inc.
140 19th Street S.W.
Sioux Center, IA 51250

Dear Dr. Kramer:

On September 23, 29, 30 and October 1 and 3, 2003, Food and Drug Administration (FDA) investigators performed an inspection at your facility, and conducted follow-up investigations through January 20, 2004. The inspection revealed that your firm manufactures a variety of products, including Oocyte Media Supplement Follicle Stimulating Hormone - Porcine Pituitaries (FSH-P), Oocyte Media Supplement Follicle Stimulating Hormone from Bovine Pituitaries, Oocyte Media Supplement Luteinizing Hormone from Bovine Pituitary Glands, Pregnant Mare Serum Gonadotropin, Gonadotropin Releasing Hormone, and Human Chorionic Gonadotropin.

Your firm holds an approved new animal drug application (NADA) for FSH-P (NADA 009-505), but has not performed the necessary steps to get this NADA approved for your manufacturing facility, as required by Title 21, Code of Federal Regulations (21 CFR), 514.8. Because this drug does not conform to its approval, it is unsafe under section 512(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) and adulterated under section 501(a)(5) of the FDCA. Your firm does not hold an approval for the other drug products and, therefore, they are likewise unsafe under section 512(a) of the FDCA and adulterated under section 501(a)(5) of the FDCA.

In your October 9, 2003, letter to FDA, you state that you have never manufactured nor marketed any of the products as drugs, and that they are produced, labeled, and sold for research use only. Whether a product is a "drug" does not depend on whether the product is used for, or intended for use in, research. Section 201(g) of the FDCA defines a drug as any article intended for use, among other things, in the diagnosis, cure, prevention, and treatment of disease in animals and/or intended to affect the structure or any function of their bodies. Since the products are intended for such uses, they are drugs regardless of whether these uses are also "research"

are intended for such uses, they are drugs regardless of whether these uses are also "research" uses. If a new animal drug is intended solely for investigational use, such as for testing *in vitro*, testing in laboratory research animals, or clinical investigations in animals, then it must comply with the applicable statutes and regulations, including section 512(j) of the FDCA and 21 CFR 511.1.

The promotional claims made by you for these products indicate that they are drugs as defined by section 201(g) of the FDCA. For example, the product name Follicle Stimulating Hormone describes not only what the product is, but also what its intended use is –to be used in connection with animal reproduction, such as increased ovulation, *in vitro* fertilization, and/or out-of-season breeding. FSH-P has been approved by FDA for reproductive purposes, your firm owns an approval for this use, 21 CFR 522.1002, and we are not aware of any non-reproductive purpose for FSH-P.

The violations listed above are not intended to be an all-inclusive list. It is your responsibility to assure that your operations are in compliance with the law. You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter of the steps you have taken to bring your operation into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

You should direct your reply to Ralph J. Gray, Compliance Officer, at the above address.

Sincerely,

Charles W. Sedgwick
District Director
Kansas City District